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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/804,778

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EXAMINER

GOON, SCARLETT Y

ART UNIT

PAPER NUMBER

1623

MAIL DATE

DELIVERY MODE

09/09/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/804,778	Applicant(s) GROSS ET AL.	
	Examiner SCARLETT GOON	Art Unit 1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 May 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 58-63, 68, 69 and 75-79 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 58-63, 68, 69 and 75-79 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This Office Action is in response to Applicants' Amendment and Remarks filed on 14 May 2009 in which claims 1-57, 64-67 and 70-74 were cancelled, claims 58, 59, 61, 68 and 69 are amended to change the scope and breadth of the claims, and new claims 75-79 are added.

Claims 58-63, 68, 69 and 75-79 are pending in the instant application and are examined on its merits herein.

Priority

This application claims priority to U.S. provisional application no. 60/456208 filed on 20 March 2003.

Oath/Declaration

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

It does not identify the mailing address of each inventor. A mailing address is an address at which an inventor customarily receives his or her mail and may be either a home or business address. The mailing address should include the ZIP Code designation. The mailing address may be provided in an application data sheet or a supplemental oath or declaration. See 37 CFR 1.63(c) and 37 CFR 1.76.

Rejections Withdrawn

Applicant's amendment, filed 14 May 2009, with respect to the rejection of claims 58-63, 68 and 69 under 35 USC § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention, has been fully considered and is persuasive because the claim has been amended to specifically indicate that it is drawn to a method of preparing a sophorolipid compound that is esterified.

These rejections are **withdrawn**.

Applicant's amendment, filed 14 May 2009, with respect to the rejection of claims 58-63, 68 and 69 under 35 USC § 112, first paragraph, for inserting new matter, has been fully considered and is persuasive because the claims have been amended to specifically indicate that the disclosed steps are performed sequentially, which is fully supported by the original Specification as filed.

These rejections are **withdrawn**.

Applicant's amendment, filed 14 May 2009, with respect to the rejection of claims 58-63, 68 and 69 under 35 USC § 112, first paragraph, for lack of enablement, has been fully considered and is persuasive because the claims have been amended to specifically indicate that the step wherein the alkoxide is added occurs prior to, and is separate from, the step in which the esterified sophorolipids are treated with a lipase.

These rejections are **withdrawn**.

The provisional rejection of claims 58-63, 68 and 69 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3, 10, 11, 13 and 14 of copending Application No. 11/020,683 is hereby withdrawn as application no. 11/020,683 was abandoned on 17 February 2009.

These rejections are **withdrawn**.

In view of the cancellation of claims 1-57, 64-67 and 70-74, all rejections made with respect to claims 1-57, 64-67 and 70-74 in the previous Office Action are **withdrawn**.

The following are new ground(s) or modified rejections necessitated by Applicants' amendment, filed on 14 May 2009, wherein the limitations in pending claim 58 as amended now have been changed; claims 59-63, 68 and 69 depend from claim 58. The limitations in the amended claims have been changed and the breadth and scope of those claims have been changed. Newly added claim 75, and claims 76-79 which depend from claim 75, is drawn to subject matter that is similar in scope to that of claims 58-63. Therefore, rejections from the previous Office Action, dated 7 November 2008, have been modified and are listed below.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 58-63, 68, 69 and 75-79 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 58-63, 68, 69 and 75-79 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are how one obtains “a dispensable sophorolipid compound” from a mixture of esterified sophorolipids, as indicated in steps (b) and (c). It is not apparent how lipase treatment of a mixture of esterified sophorolipids would result in one sophorolipid compound.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 58-63, 68, 69 and 75-79 are rejected under 35 U.S.C. 102(b) as being anticipated by journal publication by Bisht *et al.* (of record).

Bisht *et al.* disclose chemo-enzymatic synthesis of well-defined sophorolipid analogues. Sophorolipids were synthesized by fermentation of the cells of *Candida bombicola* (formerly known as *Torulopsis bombicola* as evidenced by Carr *et al.*, PTO-892, Ref. W) on glucose/oleic acid mixtures, to give lactones and open chain forms of sophorolipids (p. 780, column 2, Figure 1; p. 781, column 2, subheading “Experimental

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Section,” paragraph 1; p. 784, column 1, first paragraph). The synthesis of methyl and ethyl sophorolipid esters was conducted by reaction of the natural mixture with sodium methoxide or sodium ethoxide under reflux conditions (p. 784, column 2, Scheme 1; p. 784, column 2, subheading “Synthesis of Ester Sophorolipid Derivatives”). A detailed experimental procedure is provided for the methyl ester (compound 1), ethyl ester (compound 2), and butyl ester (compound 3) of the sophorolipids (p. 782, column 1, paragraphs 4 and 5; p. 782, column 2, first paragraph). The methyl, ethyl and butyl esters of sophorolipids were then subjected to lipase-catalyzed esterification with vinyl acetate or vinyl acrylate (p. 785, Scheme 2; p. 785-786, bridging paragraph) to yield regioselectively acylated sophorolipids. A detailed experimental procedure is provided for the synthesis of the 6',6"-diacetate derivative of the ethyl ester of sophorolipid (compound 6, p. 783, column 1, first full paragraph) butyl ester of sophorolipid (compound 7, p. 783, column 1, second full paragraph). Bisht *et al.* further disclose that sphorolipids have importance in the treatment of autoimmune disorders, regulation of angiogenesis, *in vivo* and *in vitro* antiendotoxic shock activity, and *in vivo* cancer treatment/antitumor cell activity by cytokine upregulation (p. 781, column 1, first incomplete paragraph).

In the purification of compound 9, the sophorolipid analogue was eluted using a chloroform/methanol solvent mixture. It is the Office's position that chloroform/methanol can function as an excipient. Thus, the purified product in a chloroform/methanol solution is considered to suffice as a dispensable solution of sophorolipids.

Applicants are requested to note that the recitation “having spermicidal and/or antiviral properties” is considered an inherent property of the sophorolipids. Products of identical chemical composition cannot have mutually exclusive properties. A chemical compound or composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. See *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). See also MPEP § 2112.01. It is incumbent upon the applicant to provide evidence or comparative data to the contrary.

The method for the preparation of sophorolipid analogues, disclosed by Bisht *et al.*, anticipates claims 58-63, 68, 69 and 75-79.

Response to Arguments

Applicant's arguments filed 14 May 2009 with respect to the rejection of claims 58-63, 68 and 69 made under 35 USC § 102(b) as being unpatentable over Bisht *et al.*, have been fully considered but they are not persuasive.

Applicants argue that Bisht *et al.* do not disclose a method for formulating sophorolipids having spermicidal or virucidal properties. Moreover, Applicants argue that Bisht *et al.* do not suggest that the sophorolipid esters can be formulated with an excipient for dispensing the sophorolipid compound.

With regards to the argument that Bisht *et al.* do not specifically teach that the sophorolipids have spermicidal or virucidal properties, Applicants are requested to note that the recitation “having spermicidal and/or antiviral properties” is considered an

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inherent property of the sophorolipid compound. Products of identical chemical composition cannot have mutually exclusive properties. A chemical compound or composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. See *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). See also MPEP § 2112.01. It is incumbent upon the applicant to provide evidence or comparative data to the contrary.

With regards to the argument that Bisht *et al.* do not suggest that the sophorolipid esters can be formulated as a dispensable composition, it is the Office's position that a solution comprising sophorolipids can be dispensed, and thereby meets the limitations of the instant claims. Furthermore, as the method steps taught by Bisht *et al.* are the same as that claimed in steps (a) through (d) of claims 58 and 75, wherein purification of a mixture resulting in a composition comprising the sophorolipid compound in a chloroform/methanol mixture, as taught by Bisht *et al.*, is equivalent to formulation of the sophorolipid compound with an excipient (Remington teaches that chloroform and methanol are pharmaceutically acceptable excipients, PTO-892, Ref. U) of the instant claims, the steps disclosed by Bisht *et al.* would necessarily result in a dispensable sophorolipid compound.

Thus, the rejection is still deemed proper and is therefore adhered to, with the exception of modifications made to the specific claims that are rejected to account for newly added claims in the amendment filed on 14 May 2009.

Conclusion

In view of the rejections to the pending claims set forth above, no claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SCARLETT GOON whose telephone number is 571-270-5241. The examiner can normally be reached on Mon - Thu 7:00 am - 4 pm and every other Fri 7:00 am - 12 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Shaojia Anna Jiang/
Supervisory Patent Examiner, Art Unit 1623

SCARLETT GOON
Examiner
Art Unit 1623